MAMMOGRAPHY INSPECTION PREPARATION CHECK LIST – based on Final Rules (FDA) Inspector Guidelines (v3.1- Rev 3, 11/5/99, compared 1/6/00)

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1 - 3. PRELIMINARY FACILITY AND INSPECTION INFORMATION.		
❖ **Facility Identification**		
Date of last inspection	(mm/dd/yy)	
Facility Name		
Facility ID, CFN, EIN, Street Address, City, State, & zip code.		
❖ **Facility Contacts**		
Facility Contact	(name)	
Compliance Contact (also includes the name of the lead interpreting physician)		
Billing Contact	(name)	
(VHA) Certificate Displayed?		(Y / N)
Certificate Expiration Date	(mm/dd/yy)	
❖ **X-Ray System(s) Information**		
X-Ray Unit # (supplied by ACR)		
X-Ray System Room	(# /Name)	
X-Ray unit designed for mammography?		(Y / N)
Does x-Ray system include the following?		
- Image Receptors for 2 sizes		(Y / N)
- Moving Grids for 2 sizes - Compression Paddles for 2 sizes		(Y / N)
- Compression paddles for 2 sizes		(Y / N)
- Post-Exposure Display in AEC mode (for focal spot)		(Y / N)
- Post-Exposure Display in AEC mode (for target material)		(Y / N)
X-Ray unit still in use?		(Y / N)
Is this a new[1] unit?		(Y / N)
Mammo Equipment Evaluation (by medical physicist) Done[2] ?		(Y / N)
X-Ray Manufacturer		
Model		
X-Ray Serial #		
Manufacture Date	(mm/dd/yy)	
Is the unit mobile (van, truck...)?		(Y / N / NA)
Is the unit accredited by the American College of Radiology (ACR)?		(Y / N)
Image Receptor (IR) Type	(Film/Digital/Other)	(F / D / O)
Display method	(Monitor/Laser film/Other)	(M / L / O)
❖ **Screen-Film**		
Film Manufacturer		
Film Type		
Screen Manufacturer		
Screen Type		
4. SYSTEM PERFORMANCE TESTS[3]		

[1] New: in clinical use for less than a year.
[2] (after a move or major repairs before being used to process patient films or for new units prior to a survey)
[3] see appendix A for actual questions.

A majority of tests in this category will be performed on-site by the FDA inspector! However, please complete the following questions related to system performance as completely as possible.		
❖ **Phantom Image Quality Evaluation** (Record the number of objects and artifacts)		
Background Density	(0.0 – 4.0)	
Fibers	(0 – 6 in integers or halves, e.g, 0, 0.5, 1, 1.5, ... 6)	
Fiber artifacts	(0 or 1)	
Speck groups	(whole and partial) that you can see (an integer from 0 – 5)	
Specks in the last scored group	(an integer)(2 – 6)	
Speck artifacts	(an integer from 0 – 6)	
Masses	(0 – 5 in integers or halves, e.g, 0, 0.5, 1, 1.5, ... 5)	
Mass artifacts	(0 or 1)	
❖ **Processing Evaluation** (Darkroom Fog tests)		
- (Processor) Room Name		
- (Processor) Manufacturer		
- (Processor) Model		
- Developer Manufacturer		
- Developer Type		
- Processing Cycle	(standard or extended)	
❖ **STEP tests**[4]		
❖ **Darkroom Fog Test** (for each darkroom):		
- (Dark)Room Name		
❖ **Fog test data**		
is border visible on the film.		(Y / N)
- Unfogged portion of the image	(optical density value)	
- Fogged portion of the image	(optical density value)	
- Fog Density	(calculated)	
5. QUALITY ASSURANCE (QA) PROGRAM[5]		
QA Personnel Assigned (lead I.P., QC technologist, med. physicist)?		(Y / N)
Technique Tables/Charts?		(Y / N)
Written S.O.P. 's for QC tests (with acceptable limits for each)?		(Y / N)
S.O.P. for infection control [handling blood & other infectious materials]?		(Y / N)
S.O.P. for handling consumer complaints?		(Y / N)
S.O.P for inquiring about breast implants		(Y / N)
Documentation available re: processing chemicals being consistent with the film mfgr's processing specifications?		(Y / N)
6. QUALITY CONTROL (QC) RECORDS[6]		

[4] Performed by FDA inspector see Appendix A.

[5] The quality assurance program includes, in addition to QC test records, several elements as described below:

a. Clearly assigned personnel responsibilities.

b. Procedures for QC testing with action limits that meet the regulations.

c. Mammographic technique tables or charts, including pertinent information regarding breast thickness and density, kVp-target-filter combinations for mammography, positioning, compression, exposure techniques, and appropriate image receptors.

d. Radiation safety and protection.

e. Records for corrective actions taken when QC tests fail, and records of verification tests conducted after corrective actions to assess the effectiveness of such actions.

[6] QC records are reviewed for the most recent 12-month period, or back to the date of the original certification, whichever is the shortest.

❖ **Processor Performance QC (daily)**	
Worst Month/Yr (mm/yy)	
Number of days processed mammograms (in the worst month)	
Number of processing days without recorded data	
Calculated % for not recording (# not recorded / # processed)	
Number of consecutive processing days missed	
Number of days operated out-of-limits [MD, DD:±0.15. B+F: 0.03]	
Corrective Action (C/A)[7] Documented?	(Y / N)
❖ **Fixer Retention QC (quarterly)**	
Fixer Retention QC adequate (90d)?	(Y / N)
Done at the required frequency?	(Y / N)
C/A Documented?	(Y / N)
❖ **Phantom Image QC (weekly)**	
Phantom QC records adequate (wkly)?	(Y / N)
- Number of operating weeks missing in worst consecutive 12-week period	
- C/A for failing image score [before subsequent exams] documented?	(Y / N)
Other phantom QC records/test conditions adequate?	(Y / N)
Image taken at clinical (± 1kVp) setting?	(Y / N)
Background Optical Density (at center) > or = 1.20	(Y / N)
❖ **For mobile units (van, truck, ...):**	
Performance verification after each move?	(Y / N / NA)
❖ **Compression QC (semi-annually)**	
Compression QC Adequate?	(Y / N)
Done at the required/frequency?	(Y / N)
C/A [before subsequent exams] Documented?	(Y / N)
❖ **Repeat Analysis QC (quarterly)**	
Repeat Analysis QC Adequate?	(Y / N)
- Done at the required/frequency?	(Y / N)
Evaluation done (cause of repeats determined for changes > ±2%) ?	(Y / N)
C/A (30 days) Documented? [when a given repeat % changes by > +or- 2%]	(Y / N)
❖ **Screen-Film Contact QC (semi-annually)**	
Screen-Film Contact QC Adequate?	(Y / N)
- Done at the required frequency?	(Y / N)
- All Mammography Cassettes in use tested?	(Y / N)
- 40-Mesh copper test tool used?	(Y / N)
- C/A [before subsequent exams] Documented?	(Y / N)
❖ **Darkroom Fog QC (semi-annually)**	
Darkroom Fog QC Adequate?	(Y / N)
Done at the required frequency?	(Y / N)
Background Density > or = 1.20?	(Y / N)
C/A [before subsequent exams] Documented?	(Y / N)
❖ **For Digital Mammography**[8].	
Manufacturer recommended QC procedures followed?	(Y / N)

[7] "C/A" = Corrective Action(s).

[8] For an undetermined period of time following 4/28/99, if any of the noted three questions are answered with "n", the facility will not be cited. (Since digital is not yet approved.)

Furthermore, if "Monitor" only was checked for display mode, then:		
- Monitor QC done per manufacturer 's recommendation?		(Y / N)
If "Laser film" or "Other" was checked for the display mode, then:		
- Manufacturer recommended procedures used?		(Y / N)
7. MEDICAL PHYSICIST'S SURVEY REPORT[9, 10] **(Are the following present?)**		
	1. Collimation Assessment	(Y / N)
	2. Focal Spot Size / Resolution Measurement[11]	(Y / N)
	3. kVp Accuracy and Reproducibility	(Y / N)
	4. Beam Quality (HVL measurement) [12]	(Y / N)
	5. AEC Performance Assessment[13]	(Y / N)
	6. Uniformity of Screen Speed (incl. evaluation of screen artifacts) [14]	(Y / N)
	7. Average Glandular Dose (including air kerma & AEC reproducibility)[15]	(Y / N)
	8. Phantom Image Quality Evaluation[16]	(Y / N)
	9. Artifact Evaluation[17]	(Y / N)

[9] Review the most recent medical physicist's report.

[10] In addition to these tests, the report must include:

- An evaluation of the technologist's QC tests for the period between the previous survey and the one referenced in the report.
- Test conditions, technique factors, measured or calculated results and pass/fail indication for each of the physicist's tests.
- Documentation of any problems identified and recommendations for correction actions.
- The report must be dated and signed by the same person that performed (or directly supervised the conduct of) the survey. The report may identify other participants such as trainees but such identification is not required.

Does the survey report reflect that the physicist recognized when data or analysis showed that the equipment was not performing properly, and indicated an appropriate recommendation for corrective action (s). Regardless of who corrected the problems, the facility should have a written note or report in their records indicating what was done. The facility should have retest data or documentation showing the dates of corrective actions and that any such action taken was successful.

If the physicist recommended taking corrective action regarding items that did not fail one or more required tests, and if the facility chose not to correct them, the facility must at least document that they evaluated the recommendation and the reasons for not following it.

[11] Must be done for all clinically used targets and their appropriate focal spots at the most commonly used SID, and for the system's magnification factor closest to 1.50. Until 10/28/2002, either focal spot size or resolution measurement will be acceptable, but after that date, only the resolution measurement will be acceptable.

[12] In addition to the Mo-Mo target-filter combination, it must also be done for all other clinically used target-filter combinations

[13] In addition to the Mo-Mo target-filter combination, it must also be done for Rh-Rh and W-Rh combinations (if clinically used) with 6-8 cm phantoms and the appropriate kVp(s). Until 10/28/2002, the AEC must hold the optical density variations within ± 0.30, otherwise, manual technique factors may be developed and used, but after that date, the device must keep the OD variations within + or - 0.15 and manual technique factors will not be acceptable.

[14] Must include all mammography cassettes used at the facility and must include an evaluation of screen artifacts.

[15] Must include measurement of the breast entrance air kerma (entrance skin exposure or ESE) and AEC reproducibility. The ESE and HVL measurements used in dose determination must be made at the same kVp. This kVp must be the clinical kVp(± 1) used for the standard breast. ESE measurements must use the RMI 156 (or equivalent) phantom.

[16] Must be done using the typical clinical kVp value and the RMI 156 (or equivalent) phantom. The optical density must be at least 1.2 in the center of the phantom, and the three scores for fibers, specks, and masses, must be recorded.

[17] Must be done for all cassette sizes, focal spots, and target-filter combinations that are clinically used at the facility.

	10. Radiation Output[18]	(Y / N)
	11. Decompression (compression release)[19]	(Y / N)
	12. QC Tests for New Modalities (if applicable)[20]	(Y / N)
❖ **Survey Report** :		
Survey report available?		(Y / N)
Date of previous survey	(mm/dd/yy)	
Date of current survey[21]	(mm/dd/yy)	
Survey conducted or supervised by	(name)	
Survey conducted under Interim (< 4/28/99) or Final Rules	(Interim / Final)	
Action Taken (if called for in Report)?		(Y / N)
Survey Complete?[22]		(Y / N)
Medical Physicist's Report includes the following items/tests?		(Y / N)
❖ **Focal Spot Size/Resolution Measurement**		
- Done for all clinically used focal spots?		(Y / N)
- Numerical results given?		(Y / N)
❖ **AEC Performance**		
- Reproducibility (mAs)		(Y / N)
- Numerical results given?		(Y / N)
- Performance Capability		(Y / N)
- Done for 2, 4, and 6 cm at typical kVp(s) (for these thicknesses)		(Y / N)
- Numerical results given?		(Y / N)
- Dose (including entrance air kerma reproducibility)		(Y / N)
- Exposure & HVL at same clinical kVp?		(Y / N)
- RMI 156 or equivalent phantom?		(Y / N)
- Numerical results given?		(Y / N)
❖ **Phantom Image**		
- Done at the kVp normally used clinically?		(Y / N)
- RMI 156/equivalent phantom?		(Y / N)
- 3 object scores given?		(Y / N)
❖ **Artifact Evaluation**		(Y / N)
❖ **QC Tests - New Modalities (if applicable)**		(Y / N)
❖ **Report includes the following items/tests**		

[18] Each machine used for mammography must produce a minimum of 4.5 mGy air kerma per second (513 milli Roentgen per second) at 28 kVp in the standard Mo-Mo mode when averaged over 3 seconds, at any SID the system is designed to operate and when the center of the detector is located 4.5 cm above the patient support table. For guidance purposes, one measurement at the maximum SID is acceptable. After 10/28/2002, the output must be at least 7.0 mGy air kerma under the same conditions.

[19] If the system is provided with automatic compression release after completing an exposure or after power interruption, the test must show that it has; override capability to allow maintenance of compression, 2) a continuous display of the override status, and 3) a manual emergency compression release.

[20] These are new tests that are required under the final regulations. The scope and action limits will be as set by the manufacturer of the new modality, except for the dose requirement, which has the same upper limit of 300 mrad (3 mGy).

[21] The difference between the previous and current dates should not be more than 14 months.

[22] A "Y" means all the medical physicist QC tests and/or checks were done as called for in the survey, that a pass/fail indication was given for each, that the report contains recommendations for corrective actions for items that fail in the survey, and that the critical test conditions for each test were used and numerical results (where appropriate) were given by the physicist.

Pass/fail list	(Y / N)
Recommendations for failed items	(Y / N)
❖ **Physicist's Evaluation of Technologist's QC Tests**	
- Processor QC? [for each processor]	(Y / N)
- Phantom image? [for each x-ray unit]	(Y / N)
- Repeat analysis?	(Y / N)
- Analysis of fixer retention? [for each processor]	(Y / N)
- Darkroom fog? [for each darkroom]	(Y / N)
- Screen-film contact? [for all cassettes]	(Y / N)
- Compression? [for each x-ray unit and both paddle sizes]	(Y / N)
❖ **Collimation**	
X-Ray Field - Light Field	(Y / N)
X-Ray Field - Image Receptor Alignment	(Y / N)
Compression Device Edge Alignment	(Y / N)
❖ **kVp Accuracy**	
- Done at these 3 clinical kVps? (lowest measurable, most often used, highest available)	(Y / N)
- Numerical results given?	(Y / N)
❖ **kVp Reproducibility**	
- Done at the kVp most commonly used clinically?	(Y / N)
- Numerical results given?	(Y / N)
❖ **Beam Quality (HVL) Measurement**	
- Done at the kVp most commonly used clinically?	(Y / N)
- Numerical results given?	(Y / N)
❖ **Uniformity of Screen Speed** [for all cassettes used]	
- Numerical results given?	(Y / N)
❖ **Radiation Output**	(Y / N)
❖ **Decompression**	(Y / N)

8. PERSONNEL QUALIFICATIONS[23,24]	
All required documents available?	(Y / N)

INTERPRETING PHYSICIAN[25] (**Do one for each IP**)	
Lead interpreting physician (only 1 physician may be the Lead)	(Y / N)
Name xxx [FIRST, M.I., LAST]	
UPIN Universal Provider Identification Number (when available):	
Qualifying under (Regs)	INTERIM / FINAL
❖ If **INTERIM** regulations checked: [prior to 4/28/99]	

[23] Copies of original documents in all categories are acceptable.

[24] The final regulations allow citing a facility for failing to make personnel records available during the inspection. If the facility claims to have the documents but they are not available a "C" for "Claimed" will most likely be used until a determination is made whether they can be produced or not. However, a facility should not be cited if they did not have the records because of reasons beyond their control. (will only be used on rare occasions.)

[25] If documentation is not available, proper attestation will be acceptable for the 40 (or the 60) CME's and initial experience obtained prior to October 1, 1994.

Initial Qualifications under the interim regulations met?		(Y / N)
Licensed?	[license must be current]	(Y / N / C)
Certified?		(Y / N / C)
OR		
2 Months Training?		(Y / N / C)
AND		
40 CME hours		(Y / N / C)
AND		
Initial experience adequate?	(240 ex/6 m)	(Y / N / C)
❖ If **FINAL** regulations checked:		
Initial Qualifications met?		(Y / N)
Licensed?	[license must be current]	(Y / N / C)
Certified		(Y / N / C)
OR		
3 Months Training[26]?		(Y / N / C)
60 category I CME hours?		(Y / N / C)
Initial experience adequate?	(240 exams/6 mo)	(Y / N / C)
IF "**N**", then:		
Number of exams in 24 months.		
Date completed initial requirements (under Interim or Final)[27] (mm/dd/yy)		
New Modality Training [8 hours] (if applicable)		(Y / N / C)
❖ **Continuing Experience**[28]		
Continuing experience adequate[29]?	(960 exams/24mo)	(Y / N / C)
IF "**N**", then:		
Number of exams in 24 months		
❖ **Continuing Education**		
CME credits adequate[30]?	(15/36mo)	(Y / N / C)
IF "**N**", then:		

[26] For physicians who use the 3-month full-time training as an alternate to certification, the necessary 60 hours could be part of that training.

[27] The date of completion of initial requirements is the most recent date of meeting any of these requirements or October 1994 for those who completed them prior to October 1, 1994. Once this date is determined for an individual, it must not be changed in the future for any reason.

[28] Interpreting physicians may meet the continuing experience requirement by multi-reading (reading films already read by others) and or reading and interpreting films for more than one facility.

[29] If the period from the date of completion of initial requirements to inspection date is less than 24 months, interpreting physicians who have not met the continuing experience requirement will not be cited. Those who fail to meet this requirement (after 24 months from the date of completion of the initial requirements) must not read independently until they re-qualify. They may re-qualify by reading under direct supervision within a 6-month period, the lesser of 240 patient exams or the balance needed to bring their total to 960 exams in the previous 24 months. After they re-qualify, they will be exempt from an adverse finding regarding this requirement for 6 months from their re-qualification date.

[30] If the period from the date of completion of the initial requirements to the inspection date is less than 36 months, interpreting physicians who have not met the continuing education requirement will not be cited. Those who fail to meet this requirement are prohibited from reading mammograms independently until they re-qualify. They may re-qualify by acquiring the balance needed to bring their total CME credits to I5 in the previous 36 months

Number of CME’s in 36 months	

RADIOLOGIC TECHNOLOGIST[31] **(Do one for each Mammo Tech)**	
Name yyy [FIRST, M.I., LAST]	
Qualifying under (Regs)	INTERIM / FINAL
Designated as QC Mammography Technologist?	(Y / N)
❖ If **INTERIM** regulations checked:	
Qualified under interim regulations? [prior to 4/28/99]	(Y / N / C)
- Licensed OR Certified [license/certificate must be current]	(Y / N / C)
- Training specific to mammography	(Y / N / C)
❖ If **FINAL** regulations checked:	
Initial Qualification Requirements Met?	(Y / N / C)
Licensed OR Certified?	(Y / N / C)
40 supervised hours of training adequate?	(Y / N / C)
Date completed initial requirements[32] (mm/dd/yyyy)	
New Modality Training [8 hrs.] (if applicable)	(Y / N / C)
❖ **Continuing Experience**[33]	
Continuing Experience adequate[34]? [200 exams/24mo]	(Y / N / C)
❖ **Continuing Education**	
CEU credits adequate[35]? (15/36mo)	(Y / N / C)
IF "**N**", then:	
Number of CEU's in 36 months	

[31] If documentation is not available for training, proper attestation will be acceptable only for training received prior to October 1, 1994.

[32] The date of completion of initial requirements is the most recent date of meeting any of these requirements or October 1, 1994 for those who completed them prior to October 1, 1994. Once this date is determined for an individual, it must not be changed in the future.

[33] Radiologic technologists may meet the initial or continuing experience requirement by working at more than one facility, or by co-conducting exams on patients, either with another qualified radiologic technologist or under direct supervision. However, no more than two individuals may count the same exam towards meeting either of these two requirements.

[34] If the period from the date of completion of initial requirements to inspection date is less than 24 months, radiologic technologists who have not met the continuing experience requirement will not be cited. The first time this requirement will take effect for any radiologic technologist in mammography will be after 6/30/2001. Those who fail to meet this requirement must not conduct patient mammograms independently until they re-qualify. They may re-qualify by conducting 25 patient exams under direct supervision within a 6-month period. Once they have re-qualified, they will be exempt from an adverse finding regarding this requirement for 6 months from their re-qualification date.

[35] If the period from the date of completion of the initial requirements to the inspection date is less than 36 months, radiologic technologists who have not met the continuing education requirement will not be cited. Those who fail to meet this requirement are prohibited from reading mammograms independently until they re-qualify. They may re-qualify by acquiring the balance needed to bring their total CME credits to 15 in the previous 36 months.

MEDICAL PHYSICIST[36] **(Do one for each Med. Physicist)**	
Name yyy [FIRST, M.I., LAST]	
Qualifying under	Mstrs+ / Bach / No[o]
❖ If **MASTERS** or higher was checked:	
Initial Qualification Requirements Met?	(Y / N / C)
- Certified **OR** State licensed or approved	(Y / N / C)
- Masters degree in a physical science [w/20 semester hours in physics]	(Y / N / C)
- 20 contact hrs. of training in surveys?	(Y / N / C)
- experience in conducting surveys (1 facility & 10 units)	(Y / N / C)
❖ If **BACHELOR'S** was checked:	
Qualified under **INTERIM** regulations? [prior to 4/28/99]	(Y / N / C)
- Certified **OR** State licensed or approved	
- Bachelor 's degree in a physical science[37] [w/10 semester hours in physics]	(Y / N / C)
- 40 cont. hrs. training in surveys [after Bachelor's)	(Y / N / C)
- experience in conducting surveys [after Bachelor 's](1 facility & 20 units)	(Y / N / C)
Date completed initial requirements[38] (mm/dd/yyyy)	
-New Modality Training [8 hrs.]. (if applicable)	(Y / N / C)
❖ **Continuing Experience adequate**[39]? [2 facilities & 6 units/24mo]	(Y / N / C)
❖ **Continuing Education**	
CME Credits/year adequate[40]? (15/36m)	(Y / N / C)
IF "**N**", then:	
Number of CME's in 36 months	

[36] If documentation is not available for training and experience, proper attestation will be acceptable only for training and experience acquired prior to October 1, 1994.

[37] physical science: physics, chemistry, engineering, radiation science

[38] The date of completion of initial requirements is the most recent date of meeting any of these requirements or October 1, 1994 for those who completed them prior to October 1, 1994. Once this date is determined for an individual, it must not be changed in the future should the individual meet the initial requirements through an alternate option.

[39] If the period from the date of completion of initial requirements to inspection date is less than 24 months, medical physicists who have not met the continuing experience requirement will not be cited. The first time this requirement will take effect for any medical physicist in mammography will be after 6/30/2001. Those who fail to meet this requirement must not conduct mammography facility surveys independently until they re-qualify. They may re-qualify by conducting the balance of surveys needed to meet the continuing experience requirement (2 facilities & 6 units in the previous 24 months).

[40] If the period from the date of completion of the initial requirements to the inspection date is less than 36 months, medical physicists who have not met the continuing education requirement will not be cited. Those who fail to meet this requirement are prohibited from conducting mammography facility surveys independently until they re-qualify. They may re-qualify by acquiring the balance needed to bring their total CME credits to 15 in the previous 36 months.

9. MEDICAL RECORDS	
❖ **Patient Permanent Record**[41] VHA Records Control Schedule 10-1 was updated at VA's request by Change 8, dated September 26, 1996, Item No. 114-13	
❖ **Mammography Reports**[42]	
1. System (to communicate results) adequate?	(Y / N)
a System to provide timely (w/in 30 days) medical reports[43]?	(Y / N)
b. System to provide timely (w/in 30 days) lay summaries to all patients?	(Y / N)
c. System to communicate serious cases ASAP[44]?	(Y / N)
2. Number of random written reports reviewed[45]	
3. Number (of reports) with assessment categories[46]	
4. Number (of reports) with qualified I.P. Identification	
10. MEDICAL AUDIT and OUTCOME ANALYSIS[47]	
- **ALL** positive mammograms entered in system?	(Y / N)
- Biopsy results present (or attempt to get)	(Y / N
- Is there a designated reviewing interpreting physician?	(Y / N)
The next 3 questions will not result in citations until 4/28/2001.	
- Analysis done annually?	(Y / N / X)
- Done separately for each individual?	(Y / N / X)
- Done for the facility as a whole?	(Y / N / X)

[41] These include mammograms and mammography reports and any follow-up reports. The records must be maintained for at least 5 years, or at least 10 years if no other patient mammograms are available, and for a longer period if required by state law, or until requested by the patient to transfer the records to another institution, physician, or to themselves.

[42] Under the final regulations, the facility is required to send a lay summary to all the patients to whom they provide mammography services, whether they were referred by a health care provider or not. The "lay summary" must be written in lay language that is easily understood by persons unfamiliar with medical terminology.

Also, the regulations require the facility to send a written report of the examination in a timely manner (within 30 days) to the referring health care provider or directly to the patient who does not have a referring health care provider. If the results of the examination are ‘’suspicious or highly suggestive of malignancy", the facility is required to make reasonable attempts to ensure that the results are communicated to the patient as soon as possible (ASAP).

[43] to referring health care providers

[44] (Serious: suspicious or highly suggestive cases)

[45] Select 5 random medical records (reports and films) that were done after April 28, 1999 and check if the signature and assessment categories are present for each. If any deficiencies are uncovered, examine 5 additional random reports.

[46] The assessment categories are:

- Negative
- Benign
- probably benign
- suspicious
- highly suggestive of malignancy
- incomplete: need additional imaging evaluation

[47] The facility will need to have a system or a procedure for reviewing and tracking outcomes of positive mammograms and correlating them with biopsy results. This must be done annually both individually for each interpreting physician and for the facility as a whole. Determine if the facility has a medical audit system, i.e., if it tracks, or attempts to track results of positive mammograms. How does the facility track positive mammograms to get results of biopsies. Look at a sample of a biopsy result from a positive mammogram.

Appendix A

❖ **Collimation Assessment**				
- Source to Image Distance (SID)			(cm)	
- Source to Patient Support Distance (SPSD)			(cm)	
X-Ray field / IR Misalignment (left)	(right)	(nipple)	(chest wall)	
❖ **IR / Paddle alignment**				(Y / N)
Is paddle image on the film?				(Y / N)
Compression paddle / chest wall edge of IR			(cm)	
❖ **Dose Estimate**				
Technique Factors				
- Target / filter (Mo/Mo, Mo/Rh, Other)				
- Focal Spot to Patient Support			(cm)	
- Mode		(Auto [mAs, kVp, or full] / Manual)		
Pre-Exposure SETTINGS				
kVp		mAs		
Time		Density		

Cassette Variability				
			Exposure	Exposure Time
	C. ID	mAs	(mR)	(ms)
Cassette # 1				
Cassette # 2				
Cassette # 3				

Beam Quality (HVL)		
Settings		
- kVp		
- mAs		
	Exposure Values (mR) (measured)	
	0.0 mm Al	
	0.1 mm Al	
	0.2 mm Al	
	0.3 mm Al	
	0.4 mm Al	
	0.5 mm Al	
Summary Results		
- ESE (mR)		
- C.O.V. (reproducibility)		
- Beam Quality (HVL) (mmAl)		
- Mean Glandular Dose (MGD) (mRad)		
❖ **Evaluation (STEP Test)**		
	- Ref. Step #	
	- Base + Fog	

	Lower Step #	Lower Step Den.	Higher Step #	Higher Step Den.
Ex.	xx	_._ _	xx + 1	_._ _
Strip 1				
Strip 2				
Strip 3				
Strip 4				
Test Result (Processing Speed)				(Pass / Fail)